



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

June 17, 1999

MEMORANDUM

Subject: Efficacy Review for 10492-5/Discide One Minute Disinfectant Spray

DP Barcode: D256228

From: Ibrahim S. Barsoum, Ph.D., Microbiologist
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Ibrahim S. Barsoum

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Thru: John W. Newland, Ph.D., J.D., Team Leader
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John W. Newland
8/23/99

Michele E. Wingfield, Chief
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Michele E. Wingfield
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Applicant: Palmero Health Care
Stratford, CT, USA

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt</u>
N-alkyl dimethyl benzyl ammonium chloride.....	0.12%
N-alkyl dimethyl ethyl benzyl ammonium chloride.....	0.12%
Isopropyl alcohol.....	63.25%
<u>Inert Ingredient(s)</u>	36.51%
Total	100.00

BACKGROUND:

Product manager has requested review of efficacy data (MRID 448190-01) for failure of performance reportable under FIFRA 6 (a) 2 amendment of registered product DisCide ULTRA Disinfecting Spray, EPA Reg. No. 10492-5 (one minute contact time).

RECOMMENDATIONS: EASSB findings are:

MRID 448190-01 One batch of this product (Lot No. 02089A) has failed to demonstrate efficacy against *Salmonella choleraesuis* by showing bacterial growth in 1 of 10 carriers and therefore has failed to fulfill the test requirements as a spray disinfectant which requires that a disinfectant kills bacteria in 10 out of 10 carriers (AOAC Germicidal Spray Products Test, AOAC Official Methods of Analysis, 15th edition, chapter6, 961.02)

While the data does confirm the failure of product Lot No. 02089A to demonstrate the required efficacy performance, the relevance of the reported efficacy testing failure for this product is unclear. Before any further recommendation can be made it needs to be determined what the fate of the failed production lot was after efficacy testing failure. Was this testing done as part of a quality control process and did any of the product enter the market? If the answer is yes the this should be pursued as a probable 6(a)(2) violation. However, if the material was destroyed and did not enter the market or was subsequently retested successfully then there is no further need to pursue the issue as a 6(a)(2) problem.

END